IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MYLAN INC. AND MYLAN PHARMACEUTICALS, INC., **Plaintiffs,** **v.** **BOEHRINGER INGELHEIM INTERNATIONAL GMBH and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,** **Defendants.**	**Civil Action No.** **JURY TRIAL DEMANDED** **ELECTRONICALLY FILED**

COMPLAINT

I. Nature of the Action

1. Mylan Inc. and Mylan Pharmaceuticals, Inc. (together, "Mylan") bring these claims for damages based on Defendants' elaborate scheme to eliminate competition in order to preserve wrongfully and extend its monopoly power and monopoly profits.

2. Defendants Boehringer Ingelheim International GmbH and Boehringer Ingelheim Pharmaceuticals, Inc. (collectively "Boehringer") have manufactured and sold the branded prescription drug Mirapex® since 1997. Mirapex® is indicated for Parkinson's disease and Restless Leg Syndrome, and its active pharmaceutical ingredient is pramipexole dihydrochloride. Boehringer has reaped monopoly profits on Mirapex® from 1997 to the present time.

3. Barr Pharmaceuticals, Inc. ("Barr") and Mylan each developed a generic pramipexole drug to sell in competition with Boehringer. Barr was the first company to be ready to sell a generic version of Mirapex®, which accords it the exclusive right to sell a generic

product for 180 days. After Barr has sold its generic product for 180 days, other firms are then free to sell their own generic versions.

4. To preserve its monopoly position, Boehringer has taken a number of actions that, alone and in combination, have raised barriers and unlawfully prevented competition from generic drugs from reducing its monopoly profits. Boehringer obtained U.S. Patent No. 4,866,812 (the "'812 Patent"), which it knew or should have known was invalid because the patent claimed the same compound for which Boehringer had already received patent protection in U.S. Patent No. 4,843,086 (the "'086 Patent"). Boehringer listed the '812 Patent in the FDA Orange Book to raise entry barriers, knowingly sought a five-year extension of the invalid '812 Patent, and sued both Barr and Mylan in the United States District Court for the District of Delaware for allegedly violating this invalid patent with their generic pramipexole products to keep them off the market.

5. After putting the Delaware District Court and the parties through three years of unnecessary litigation and a full trial, Boehringer filed on the last day of trial a terminal disclaimer of the '812 Patent in favor of the '086 Patent, even though the '086 Patent had expired almost two years earlier. Notwithstanding Boehringer's attempts to evade a judicial decision, the Delaware District Court declared the '812 Patent invalid by clear and convincing evidence because of nonstatutory double patenting with respect to the '086 Patent. The Court also found the terminal disclaimer to be ineffective and untimely and entered judgment against Boehringer.

6. Despite this setback, Boehringer simultaneously appealed the decision to the United States Court of Appeals for the Federal Circuit and reached a settlement agreement with Barr pursuant to which Barr agreed: (i) not to contest the appeal; (ii) to forgo its right to launch a competing product until at least 2010; and (iii) to enter into a separate business deal with

Boehringer. The combination of the litigation appeal and the agreement with Barr was designed to and has postponed the beginning of Barr's six-month exclusivity period and further delayed Mylan's entry into the market until at least six months after Barr's entry in 2010.

7. Notwithstanding the Delaware District Court decision finding that the '812 patent was invalid, Boehringer filed an additional lawsuit in January 2009 in the United States District Court for the District of New Jersey, claiming that Mylan has infringed its invalid '812 Patent. The New Jersey District Court granted Mylan's motion to dismiss this litigation in May 2009. Boehringer filed a notice of appeal of this decision to the Federal Circuit on June 10, 2009.

8. The purpose and effect of these acts and this overall scheme was to unlawfully monopolize the market for Mirapex® and its generic equivalents. Boehringer's action has harmed Mylan by blocking it from selling competitive products from as early as 2007 and requiring Mylan to incur unnecessary legal expenses. Boehringer's actions have injured the market and consumers by eliminating choice and preventing lower cost pharmaceuticals from reaching the market.

II. The Parties

9. Plaintiff Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. It is the third largest generic pharmaceutical company in the world.

10. Plaintiff Mylan Pharamaceuticals, Inc. is a corporation organized and existing under the laws of the State of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. It is a wholly-owned subsidiary of Mylan Inc.

11. Defendant Boehringer Ingelheim International GmbH is a limited partnership organized and existing under the laws of Germany, having its principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

12. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

13. Boehringer is the record owner of the '812 Patent and of the '086 Patent.

III. Jurisdiction and Venue

14. Mylan brings this suit as an action for damages for Boehringer's violations of Section 2 of the Sherman Act, 15 U.S.C. § 2. Mylan brings these claims pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15. Mylan also brings claims for the violation of the laws of West Virginia and Pennsylvania.

15. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 as well as the U.S. antitrust laws, including Section 2 of the Sherman Act, 15 U.S.C. § 2; and Section 4 of the Clayton Act, 15 U.S.C. § 15. The Court has jurisdiction over the state law claims under 28 U.S.C. § 1367 because those claims are so related to the federal claims that they form part of the same case or controversy.

16. Venue is proper in this judicial district pursuant to 15 U.S.C. §§ 15 and 22; and 28 U.S.C. § 1391.

17. Boehringer is engaged in the sale of Mirapex®, a pramipexole product, in interstate commerce and in this judicial district. As a direct and proximate result of its anticompetitive conduct, Boehringer has blocked Mylan's participation in interstate commerce in the manufacture, marketing and/or sale of Mylan's pramipexole products, and has extended its

monopoly position in sales of pramipexole products in this judicial district and in interstate commerce throughout the United States.

IV. The Hatch-Waxman Act and Competition between Branded Drugs and Generic Equivalents

18. The FDA regulates the approval, manufacture, and commercial sale of pharmaceuticals in the Unites States pursuant to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (the "Act"), which was first passed in 1938. No branded or generic pharmaceuticals may lawfully be sold commercially in the United States without FDA approval. Congress passed the "Hatch-Waxman Amendments" to the Act in 1984 to simplify and shorten the approval process for generic versions of branded drugs.

19. The Hatch-Waxman Amendments permit generic drug manufacturers to file an Abbreviated New Drug Application ("ANDA") that expedites the drug approval process. Rather than go through full clinical trials, as is required for a branded drug, an ANDA filer need only show that its drug is bioequivalent (within a defined range) to the branded drug. If the generic drug is bioequivalent and is the same dosage strength and form as the branded drug, it is deemed to be an "AB-rated equivalent" to the branded drug. Many states have "automatic substitution" laws that require pharmacists to substitute AB-rated generic versions for prescriptions written for branded drugs unless the prescribing physician specifically requests otherwise.

20. The manufacturer of a branded drug is required to identify all patents that it asserts cover the branded drug in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book").

21. If an ANDA applicant seeks approval to market a drug before the expiration of one or more patents listed in the Orange Book as covering that drug, the ANDA must contain a

certification as to each, "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Such a certification is known as a "Paragraph IV Certification."

22. The filing of a Paragraph IV Certification permits the holder of any patent identified in the Orange Book, as purportedly covering the listed drug, to assert a cause of action for patent infringement against the ANDA applicant. If such an action is brought within 45 days from receipt of notification of any Paragraph IV Certification, the FDA cannot grant final approval of the ANDA until the earlier of (i) 30 months from the patent-holder's receipt of notification of the Paragraph IV Certification or (ii) the date on which a final judgment is entered in the patent infringement case holding that such patent is invalid, not infringed, or unenforceable. In practice, this generally means that a manufacturer of a branded drug can automatically prevent entry of a generic drug for 30 months simply by filing a patent infringement litigation, *regardless of whether or not that claim has any merit.*

23. If an ANDA has satisfied all FDA regulatory requirements and the 30-month stay period has not expired, the FDA will grant tentative approval of the ANDA. The FDA's grant of tentative approval means that the FDA would have granted a final approval absent the stay period. The ANDA applicant can sell the generic product in the United States only upon receipt of final approval from the FDA, not upon receipt of tentative approval.

24. Upon the ANDA applicant's receipt of tentative approval from the FDA, the 30-month stay period becomes a statutory barrier to market entry by the ANDA applicant.

25. The Hatch-Waxman Amendments further provide that the first ANDA filed with a Paragraph IV Certification for a generic version of a branded drug listed in the Orange Book receives a 180-day period of marketing exclusivity ("180-day exclusivity"). During the first

applicant's 180-day exclusivity period, no other generic manufacturer may enter the market. The 180-day exclusivity period begins to run either from the first date on which the ANDA product is commercially marketed or the date on which a court enters a final, non-appealable decision of invalidity or non-infringement regarding the listed patent, whichever is earlier. If there is no commercial launch by the first ANDA filer within 75 days of a final court decision of invalidity or non-infringement, the 180-day exclusivity period is forfeited.

V. Relevant Market and Market Power

26. Mirapex® is manufactured, marketed and sold by Boehringer in the United States. On July 1, 1997, Boehringer received approval from the FDA for Mirapex®, for the treatment of idiopathic Parkinson's disease. In November 2006, the FDA also approved Mirapex® for the treatment of moderate to severe Restless Leg Syndrome.

27. To date, the only other companies to receive either tentative or final approval from the FDA to market competitive pramipexole products are Mylan, Barr, and Alembic Limited. Mylan received tentative approval for its generic pramipexole product on May 8, 2007. Barr received tentative approval for its generic pramipexole product on October 29, 2007 and final approval on February 19, 2008. Alembic received tentative approval for its generic pramipexole product on July 20, 2008. But for the unlawful conduct of Boehringer, Mylan would offer a generic product that would compete with Mirapex®.

28. The generic pramipexole drugs developed by Mylan, Barr and Alembic are AB-rated equivalents to Boehringer's branded Mirapex® drug, which means they are considered bioequivalent substitutes and may be automatically substituted for Mirapex® under certain state laws. As a result, the AB-rated equivalents are perfect competitive substitutes for Mirapex®. No other drugs may be substituted for Mirapex®.

29. The generic pramipexole products would be priced substantially below the price Boehringer charges for Mirapex®.

30. Because Mirapex® and its AB-rated equivalents are competitive substitutes and would be offered for a lower price, upon the entry of either or both of those products they would divert substantial sales from Mirapex®, which would benefit consumers, patients, and government programs.

31. The relevant product market in which to assess the anticompetitive effects of Boehringer's conduct is the market for Mirapex® and its AB-rated equivalents (the "Relevant Market").

32. The relevant geographic market is the United States and its territories. The FDA regulatory process for approving drugs for sale in the United States, and the fact that marketing, sales and distribution of drugs occurs on a nationwide basis, establish the boundaries of the geographic market.

33. Since it first launched Mirapex® in 1997, Boehringer has possessed monopoly power in the Relevant Market with a market share of 100 percent. It has the ability to control price and exclude competitors. Only AB-rated generic equivalents to Mirapex® can be substituted for Mirapex®.

VI. Boehringer's Wrongful Scheme

34. Boehringer has engaged in a sustained and multi-faceted scheme to ensure that it would reap monopoly profits on its Mirapex® drug for as long as possible by raising barriers to entry and working to delay and prevent competition from generic drugs.

35. In November 1987, Boehringer applied for the '086 Patent, covering a method of treatment using tetrahydro-benzothiazoles, including the compound pramipexole.

36. While the application for the '086 Patent was pending, Boehringer filed a second application for the '812 Patent, covering the pramipexole compound without reference to methods of treatment. A patent obtained through "double patenting" is invalid and cannot be infringed.

37. On June 27, 1989, the U.S. Patent and Trademark Office ("PTO") approved the '086 Patent, and on December 12, 1989 the PTO approved the '812 Patent. Both patents were issued to the same inventors, who were employees of Boehringer. Upon information and belief, Boehringer applied for the '812 Patent despite knowing that it covered the same compound claimed in the '086 Patent, and Boehringer knew or should have known that the '812 Patent would be invalid for double patenting.

38. Pursuant to the Hatch-Waxman Amendments, Boehringer listed both patents in the FDA's Orange Book with regard to Boehringer's product, Mirapex®. The '086 Patent and '812 Patent share the same specification and same title, "Tetrahydro-Benzothiazoles, The Preparation Thereof and Their Use as Intermediate Products or as Pharmaceuticals." Upon information and belief, Boehringer wrongfully listed the '812 Patent in the Orange Book because Boehringer knew, or should have known, that the '812 Patent was invalid.

39. Section 156 of the United States Patent Act allows for the term of a patent to be extended where the commercial exploitation of the patented product is delayed by the need to seek regulatory approval, such as approval by the FDA. The duration of the extension is the period between the date the patent was granted and the date of marketing approval. Only one patent per approved product may be extended, and the patent to be extended must be unexpired.

40. On July 28, 1997, Boehringer sought an extension under Section 156 of the United States Patent Act for its invalid '812 Patent, which was to expire on December 12, 2006.

Boehringer's extension request was granted and the '812 Patent's expiration date was extended to March 25, 2011.

41. Boehringer chose to attach the Section 156 extension to its later-filed '812 Patent instead of the '086 Patent as part of its scheme to extend its monopoly as far into the future as possible, to March 25, 2011.

42. On May 27, 2005, Barr filed an ANDA seeking FDA approval to market and sell a generic pramipexole 0.25 mg product that would be AB-rated to Mirapex®. On June 24, 2005, Barr filed an amendment to its ANDA seeking FDA approval to market and sell generic pramipexole 0.125, 0.5, 1.0, and 1.5 mg products that would be AB-rated to Mirapex®.

43. On August 10, 2005 and September 12, 2005 Barr advised Boehringer via a letter that Barr had filed a Paragraph IV Certification stating that Boehringer's '812 Patent covering pramipexole was either invalid or would not be infringed by Barr's generic product. Boehringer sued Barr to enforce the '812 and the '086 Patents, even though Boehringer's claims based on the '812 Patent were objectively baseless, because that patent was invalid and an invalid patent cannot be infringed. Boehringer brought the infringement suit for the purpose of extending its monopoly and delaying or thwarting generic entry.

44. As mandated by the Hatch-Waxman Amendments, the suit against Barr automatically triggered a 30-month stay of any approval of generic pramipexole until the earliest of the expiration of 30 months from Boehringer's receipt of notice of the Paragraph IV Certification, or a final district court determination of non-infringement or invalidity.

45. On August 26, 2005, Mylan filed the second ANDA seeking approval to market and sell generic pramipexole 0.125, 0.25, 0.5, 1.0, and 1.5 mg products that would be AB-rated to Mirapex®. Mylan informed Boehringer that it had filed a Paragraph IV Certification via letter

on October 26, 2005 and, within 45 days, was sued by Boehringer for patent infringement relating to the '812 Patent. Boehringer's filing of an infringement lawsuit against Mylan after receiving Mylan's notice thus began an automatic 30-month stay from the date it received Mylan's notice letter, preventing Mylan from receiving FDA approval and launching its generic pramipexole products.

46. On June 26, 2006, the '086 Patent expired. Nonetheless, Boehringer continued to pursue its patent infringement claims against Mylan and Barr on the basis of the '812 Patent, forcing Mylan and Barr to litigate through a bench trial on the merits.

47. At the conclusion of the bench trial on March 11, 2008, after Boehringer had subjected Mylan to almost three years of baseless litigation, Boehringer made the calculated decision to file a terminal disclaimer with the PTO.

48. A terminal disclaimer is a binding statement made with the PTO when more than one patent has been obtained by the inventor on the same invention. The disclaimer states that the later patent will expire at the same time as the earlier patent.

49. Terminal disclaimers are used to cure double patenting problems and act to tie the affected patents together so that they expire on the same date, thereby preventing the inventor from obtaining a second patent term for claims that are not patentably distinct from the claims of the first patent.

50. Although the proper filing of a terminal disclaimer ordinarily can cure double patenting, Boehringer's disclaimer was improperly filed almost two years after the earlier-issued '086 Patent had expired and three years after Boehringer brought its sham patent infringement claims.

51. On June 26, 2008, the Delaware District Court (Judge Farnan) issued an Opinion and Order in *Boehringer Ingelheim Int'l GmbH v. Barr Labs. Inc., et al.*, 562 F.Supp.2d 619 (D. Del. June 26, 2008), holding by clear and convincing evidence that the '812 Patent was invalid due to nonstatutory double patenting. The Delaware District Court found that it would be impossible for one to practice the claims in the '086 Patent without necessarily using or forming the compounds claimed in the '812 Patent and held, "allowing Boehringer to secure a new patent on a compound which was itself specifically identified in the earlier method claims of the '086 patent is precisely the type of monopolistic conduct the doctrine of nonstatutory double patenting was designed to prevent." *Id.* at 639.

52. The Delaware District Court also concluded that the terminal disclaimer filed by Boehringer was "ineffective" because a terminal disclaimer cannot overcome an obviousness-type double patenting problem if the earlier patent has expired. *Id.* at 631-32.

53. The Delaware District Court expressed concern about the timing of Boehringer's filing of the terminal disclaimer, because an "unreasonable delay" in filing can extend a monopoly, which is counter to the purpose of the terminal disclaimer provision, and because "extensive delay in filing a document which may ultimately moot a double patenting issue can have harsh effects on the judicial system as a whole resulting in gamesmanship during trial, and/or a waste of the Court's and the parties' resources." *Id.* at 632 n.8.

54. Boehringer waited until the last possible moment, after extensive time and cost to the parties and the court, to file the terminal disclaimer in the hope of avoiding a judicial decision on the '812 Patent and for the purpose of wrongfully extending its monopoly as long as possible.

55. Even after the Delaware District Court found the '812 Patent invalid, Boehringer continued its elaborate scheme to maintain its monopoly position by delaying the entry of a final judgment and appealing Judge Farnan's decision to the Federal Circuit.

56. Although the Delaware District Court decided the case on June 26, 2008, it did not enter a final judgment until September 18, 2008, due in part to conduct by Boehringer that Boehringer intended to create delay before an appeal, in order to further extend its monopoly.

57. In its appeal to the Federal Circuit, Boehringer does not challenge or even address Judge Farnan's decision holding that the '812 Patent represented double-patenting over the '086 Patent.

58. At oral argument in Boehringer's appeal to the Federal Circuit, two members of the panel recognized that permitting a terminal disclaimer to a patent after the patent's expiration would allow patent holders to "misuse the patent during the period before the disclaimer to discourage competition," and questioned Boehringer's counsel whether that should be allowed.[1]

59. At the same time it elected to appeal the decision of Judge Farnan, Boehringer also reached a settlement with first-filer Barr that has had the effect of further delaying all entry into the Relevant Market. The full terms of the agreement between Boehringer and Barr are not public, but upon information and belief Barr agreed not to launch its generic pramipexole products before 2010, which is approximately the time in which the Federal Circuit can be expected to rule on Boehringer's appeal. Nor has Barr relinquished its rights to the 180-day exclusivity period. As a result, instead of being able to launch a generic product about six months after Barr's launch following the Delaware District Court decision (*i.e.*, launch at the end

[1] Oral argument, *available at* http://oralarguments.cafc.uscourts.gov/mp3/2009-1032.mp3.

of 2008), unless Barr relinquishes or forfeits its exclusivity Mylan and other potential manufacturers of generic pramipexole products will be prevented from launching competing generic pramipexole products until either 75 days from the affirmance of the Federal Circuit; or, if Barr launches its ANDA pramipexole products within those 75 days, 180 days after Barr's commercial launch. Boehringer's ploy in appealing the sham patent litigation and reaching an agreement with Barr effectively has ensured that generic competition to Mirapex® will continue to be significantly delayed.

60. Boehringer simultaneously agreed with Barr to a patent settlement and business transactions relating to the prescription drug Aggrenox®.

61. On January 26, 2009, notwithstanding the decision by Judge Farnan that the '812 Patent is invalid on the grounds of nonstatutory double patenting, Boehringer filed in New Jersey District Court a new complaint against Mylan alleging infringement of the '812 Patent with respect to a 0.75 mg pramipexole product. The purpose of this litigation was to further delay Mylan's launch of a generic 0.75 mg pramipexole product, and to cause Mylan to incur additional expense defending against meritless litigation. Boehringer knew or should have known that this new litigation based on its '812 Patent was objectively baseless. After hearing oral argument, the New Jersey District Court granted Mylan's motion to dismiss from the bench in May 2009. Boehringer filed a notice of appeal of this decision to the Federal Circuit on June 10, 2009.

62. In sum, in furtherance of its overall scheme to monopolize the Relevant Market in violation of the antitrust laws, Boehringer took a number of steps including obtaining PTO approval of the '812 Patent knowing it was invalid; wrongfully listing the '812 Patent in the Orange Book; choosing to extend the term of the invalid '812 Patent; filing and pursuing

objectively baseless patent infringement claims based on the '812 Patent; forcing Mylan to litigate through trial before attempting to cure the double patenting by filing an improper and belated terminal disclaimer; appealing the decision of the Delaware District Court to the Federal Circuit for the purpose of delaying generic entry; filing additional litigation based on the invalidated '812 Patent in the New Jersey District Court; and reaching a settlement with Barr that further delayed generic competition and allowed Boehringer to extend its monopoly and receipt of monopoly profits.

VII. Injury to Competition, Antitrust Injury and Damages

63. Boehringer's conduct allowed it to eliminate competition and wrongfully extend its monopoly power, and to continue to charge supra-competitive prices for Mirapex®. But for Boehringer's conduct, Mylan would have launched its generic pramipexole product on May 8, 2007, the date for which it received tentative approval by the FDA. As a result, Mylan has suffered reduced profits from sales it otherwise would have made of its generic pramipexole product. Doctors, patients and health care providers, and federal and state government programs, also have been denied the opportunity to prescribe or purchase less expensive generic pramipexole products. As a direct and proximate result of Boehringer's conduct, patients in the United States have paid and will continue to pay supra-competitive prices for pramipexole products.

64. When a physician prescribes a pharmaceutical product, such as Mirapex®, under many state laws pharmacies must automatically fill the prescription with an AB-rated generic substitute if one is available, unless the physician specifically directs otherwise. These automatic substitution laws are intended to reduce the cost of drugs for consumers because generic substitutes are priced substantially below branded pharmaceuticals.

65. But for Boehringer's unlawful scheme, Mylan would have received FDA final approval and would be selling a generic version of Mirapex®. Because Mylan's competing pramipexole product would be priced below and would be AB-rated equivalent to Boehringer's Mirapex® (and therefore eligible for automatic substitution), Mylan would capture significant sales immediately upon entry into the Relevant Market.

66. If competition from generic pramipexole had been allowed, physicians and consumers and other purchasers would have had more options, and would have bought Mirapex® and/or generic pramipexole at lower prices than they were charged for Mirapex®.

67. Boehringer's conduct in furtherance of its scheme to monopolize and prevent competition directly and proximately is foreclosing Mylan from the Relevant Market and is causing injury to Mylan in at least the following ways:

(a) Mylan has been forced to expend, and is continuing to expend, substantial sums to defend multiple patent litigations regarding the '812 Patent (including the appeal), as well as incur the expenses of this litigation;

(b) Mylan has lost and will continue to lose millions of dollars in profits from lost sales by virtue of its foreclosure from the Relevant Market and Boehringer's prevention of generic competition in the Relevant Market;

(c) Mylan will be prevented from developing new customer relationships and competitive advantages with respect to generic versions of Mirapex® in the Relevant Market by virtue of Boehringer's improper conduct that is allowing Boehringer to market and sell Mirapex® unimpeded by competition; and

(d) Mylan is losing valuable goodwill due to the competitive disadvantage resulting from its foreclosure from the Relevant Market.

68. Boehringer's conduct is continuing, and without the intervention of the Court, Mylan faces continuing and irreparable damage and injury from its continued exclusion from the

Relevant Market. In addition, Mylan has suffered and continues to suffer monetary damages in an amount to be determined at trial.

69. Mylan currently does not know the full extent of its damages, but it is believed that the total of the actual damages from the unlawful conduct alleged herein will be substantial. Mylan reserves the right to amend the present Complaint at such time as Mylan has ascertained more precisely the full extent of its damages.

70. The injury to competition flows directly from Mylan's injuries, and both Mylan's injuries and the injury to competition result directly from Boehringer's anticompetitive conduct.

71. The injury to Mylan resulting from Boehringer's wrongful conduct constitutes antitrust injury.

Count I – Monopolization (Sherman Act Section 2)

72. Mylan repeats and re-alleges the allegations of paragraphs 1-71 as though alleged herein.

73. Boehringer has monopoly power in the Relevant Market.

74. Boehringer has engaged in acts that separately, and as part of an overall scheme of exclusionary conduct, have wrongfully extended its monopoly of the Relevant Market, including:

(a) Obtaining PTO approval for the '812 Patent, which Boehringer knew was invalid and unenforceable;

(b) Wrongfully listing the '812 Patent in the Orange Book;

(c) Obtaining an extension of the '812 Patent;

(d) Filing and pursuing baseless patent infringement claims on which no reasonable litigant could expect to prevail;

(e) Forcing Mylan to litigate through trial before filing a terminal disclaimer with the PTO;

(f) Improperly filing a terminal disclaimer on the '812 Patent when the '086 Patent already had expired;

(g) Appealing its sham litigation to the Federal Circuit for the purpose of delaying generic entry;

(h) Settling its infringement claims with Barr in a way that extended Boehringer's monopoly position in the Relevant Market;

(i) Filing further baseless litigation alleging infringement of its invalid '812 Patent in New Jersey District Court; and

(j) Taking other actions in support of its overall scheme.

75. Boehringer engaged in this conduct with a specific intent to monopolize the relevant market.

76. Boehringer's conduct occurred in, and is having a substantial effect on, interstate commerce.

77. As an intended, direct, foreseeable and proximate result of Boehringer's wrongful, anticompetitive conduct, there has been cognizable injury both to Mylan and to competition. Boehringer's conduct has also caused and/or will cause harm to other actual and/or prospective competitors in the Relevant Market, and to purchasers and prospective purchasers in the Relevant Market.

78. As a direct and proximate cause of Boehringer's exclusionary and anticompetitive conduct, Mylan has been injured and has sustained damages, and will continue to sustain damages in the future.

79. The injury to Mylan constitutes antitrust injury.

80. Mylan is entitled to recovery for its damages.

Count II – Attempted Monopolization (Sherman Act Section 2)

81. Mylan repeats and re-alleges the allegations of paragraphs 1-80 as though alleged herein.

82. Boehringer has attempted to monopolize the Relevant Market.

83. Boehringer has a specific intent to monopolize and has taken affirmative exclusionary acts in furtherance of its attempt to monopolize the Relevant Market.

84. There is a dangerous probability that Boehringer will succeed in its attempt to monopolize the Relevant Market.

85. Boehringer's conduct occurred in, and is having a substantial effect on, interstate commerce.

86. As a direct and proximate cause of Boehringer's exclusionary and anticompetitive conduct, Mylan has been injured and sustained damages.

87. The injury to Mylan constitutes antitrust injury.

88. Mylan is entitled to recover for its damages.

Count III – Monopolization (W. Va. Code, Section 47-18 -4)

89. Mylan repeats and re-alleges the allegations of paragraphs 1-88 as though alleged herein.

90. This count is brought pursuant to W. Va. Code, Section 47-18-4.

91. Boehringer has engaged in acts that established, maintained or used a monopoly or an attempt to establish a monopoly of trade or commerce in the Relevant Market.

92. Boehringer engaged in this conduct with the purpose of excluding competition or controlling, fixing or maintaining prices.

93. Boehringer's conduct has affected trade or commerce, which occurred in part within West Virginia.

94. As a direct and proximate cause of Boehringer's anticompetitive conduct, Mylan has been injured and has sustained damages, and will continue to sustain damages in the future.

95. Mylan is entitled to recovery for its damages.

Count IV – Tortious Interference with Prospective Contractual Relations

96. Mylan repeats and re-alleges the allegations of paragraphs 1-95 as though alleged herein.

97. Mylan is an established manufacturer and seller of pharmaceutical products. Mylan has established relationships with customers and strong distribution channels for its products. But for Boehringer's wrongful and exclusionary conduct, Mylan would have entered the market with an AB-rated generic equivalent to Mirapex®, and would have achieved substantial sales and made significant profits.

98. Mylan has valid business expectancies concerning the sale of its generic pramipexole products to various purchasers upon Mylan's receipt of FDA final approval of its ANDA.

99. Boehringer knows that Mylan has valid business expectancies relating to the purchase of Mylan's pramipexole products upon receipt of FDA final approval.

100. Boehringer, through the conduct alleged above, has intentionally and tortiously interfered with Mylan's valid business expectancies, and Boehringer's interference has prevented Mylan from selling, and has prevented Mylan's customers from purchasing, Mylan's pramipexole products.

101. Boehringer's conduct lacks privilege or justification.

102. Boehringer's conduct is outrageous, because of Boehringer's ill motive and/or reckless indifference to the rights of others.

103. As a direct and proximate cause of Boehringer's conduct, Mylan has been injured and sustained damages.

104. Mylan is entitled to actual and punitive damages.

Prayer for Relief

WHEREFORE, Mylan respectfully requests that the Court enter a judgment in its favor and against Boehringer and grant the following relief:

A. Entering a judgment that Boehringer has violated Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2;

B. Entering a judgment that Boehringer has violated the laws of West Virginia and Pennsylvania;

C. Entering a judgment that Boeheringer has violated W. Va. Code, Section 47-18-4;

D. Entering a judgment that Boehringer has tortiously interfered with Mylan's valid business expectancies;

E. Entering an Order, pursuant to the Sherman Antitrust Act, 15 U.S.C. § 1, et seq., the Clayton Act, 15 U.S.C. § 15, and the laws of Pennsylvania and West Virginia, awarding damages, costs of suit, interest and attorney's fees to Mylan, and that Mylan's damages be trebled;

F. Declaring this case exceptional under 35 U.S.C. § 285 and awarding Mylan its attorney fees and costs;

G. Awarding Mylan actual and punitive damages as a result of Boehringer's intentional interference with Mylan's valid business expectations; and

H. Awarding Mylan such further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Mylan demands a trial by jury as to all issues of right to a jury.

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By: _____

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